

EXHIBIT B

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/252,385	09/24/2002	Joachim Brendel	02481.1687-02	6107

22852 7590 03/21/2003

 FINNEGAN, HENDERSON, FARABOW, GARRETT &
 DUNNER LLP
 1300 I STREET, NW
 WASHINGTON, DC 20006

EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

MAR 25 2003

FINNEGAN, HENDERSON, FARABOW,
GARRETT AND DUNNER, LLP

MAR 25 2003

 Docketed 3-28-03 Attorney CHE/BCO/SSS
 Case 2481-1687-02
 Due Date 6-21-03
 Action RESPONSE / ELECTION
 By [Signature]

PTO-90C (Rev. 07-01)

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Office Action Summary	Application No. 10/252,385		Applicant(s) BRENDAL ET AL.	
	Examiner RITA J. DESAI		Art Unit 1625	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) 8 and 10-17 is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 9 is/are rejected.

7) ☒ Claim(s) 1-7, 18 and 19 is/are objected to.

8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/698,078.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s) <u>4</u> . 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other:
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DETAILED ACTION***Priority***

Applicants priority to the parent US 09/698,078 is acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7,9, 18 and 19 all in part drawn to compounds and composition and one method of use, wherein R1 is of the formula COR11 or SO2R10, and R10 and R11 have the formula R9 wherein R9 is a phenyl, naphthyl or a biphenyl or a cycloalkyl, R3 is CyH2y-R16 and R16 is a phenyl, naphthyl or a biphenyl or a cycloalkyl, R30 and R31 do not together form a chain, and R3 and R4 do not together form a ring, classified in class 564,514, subclass 155, 617. A further election of the species of example 4c on page 55 of the specifications was elected.
- II. Claims 8,15,16 and 17, drawn to complex compositions, classified in class 514 and various subclass.
- III. Claims 10,11-14, drawn to methods of treating using these compounds, classified in class 514 and various subclasses.
- IV. Claims 1-19 in part, drawn to compounds compositions and method of treating wherein the various R's are other than in group I, classified in various classes and subclass.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

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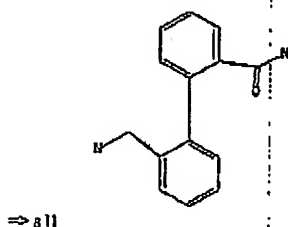
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functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the compounds do not have a novel common core. The different variables R1-R31 give rise to numerous permutations and combinations that a 102 reference on one group would not be a 103 on the other group.

When a preliminary search was done on the core it gave numerous iterations indicating that the core is not the applicants contribution over the prior art.



SAMPLE SEARCH INITIATED 18:29:03 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 314 TO ITERATE

100.0% PROCESSED 314 ITERATIONS 38 ANSWERS

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE **COMPLETE**

BATCH **COMPLETE**

PROJECTED ITERATIONS: 5217 TO 7343

Inventions I, IV and II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are numerous drugs that treat arrhythmia. Such as

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A synthetic antiarrhythmic drug, N-methyltetrahydrofurfuryl-4,4-(4'-methoxyphenyl) (3"-methyl-4"-methoxyphenyl)butylamine-2 hydrochloride.

AU Charlier, R.

CS Labaz Labs., Brussels, Belg.

SO Arch. intern. pharmacodynamie (1958), 115, 183-200

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IV, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr Steven Scott on 3/18/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7, 9, 18 and 19 all in part drawn to compounds and composition and one method of use, wherein R1 is of the formula COR11 or SO2R10, and R10 and R11 have the formula R9 wherein R9 is a phenyl, naphthyl or a biphenyl or a cycloalkyl, R3 is CyH2y-R16 and R16 is a phenyl, naphthyl or a biphenyl or a cycloalkyl, R30 and R31 do not together form a chain, and R3 and R4 do not together form a ring, classified in class 564,514, subclass 155, 617. A further election of the

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species of example 4c on page 55 of the specifications was elected and the examiner made the above group based on fair interpretation of the principles of the chemical and legal equivalence.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants preserve their right to file a divisional on the canceled, non-elected subject matter, without prejudice in due course.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 9 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IC50 values in different solutions, does not reasonably provide enablement for therapy or prophylaxis of K+ channel mediated illness!. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands , 858 F. 2d 731,737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

The claims recite therapy or prophylaxis of K+ channel mediated illness ! The specifications are devoid of any guidance as which illness they refer to . Also prophylaxis is same as prevention and there is no guidance as to how one would prevent an illness if one does not know if they have it or will in the future get it.

The only illness referred to is arrhythmia , atrial fibrillation, atrial flutter.

There is very little predictability in the art that any and all illnesses , included the ones not discovered as yet can be treated by K+ channel mediation.

Applicant can over come this rejection by limiting it to treating these illness.

Conclusion

The claims limited to group I is found to be allowable over the prior art of record.

The claims are objected to as containing non-elected subject matter. If applicants amend the claims to the elected group and amend claim 9 to overcome the 112 issues the claims may be allowable.

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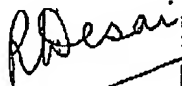
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



R.D.
March 20, 2003

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Interview Summary	Application No.	Applicant(s)	
	10/252,385	BRENDLE ET AL.	
	Examiner	Art Unit	
	RITA J. DESAI	1625	

All participants (applicant, applicant's representative, PTO personnel):

(1) RITA J. DESAI (3) _____

(2) Steven Scott (4) _____

Date of Interview: 19 March 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative)

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
If Yes, brief description: _____

Claim(s) discussed: _____

Identification of prior art discussed: _____

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants elected a species of compound 4c page 55 for the examiner to make a restriction group.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required